

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

UNITED STATES OF AMERICA,

Plaintiff,

v.

BIO HEALTH SOLUTIONS, LLC

and

MARK GARRISON,

Defendants.

Case No.: 3:15-cv-00354-HDM-VPC

~~(Proposed)~~ ORDER GRANTING
CONSENT DECREE OF PERMANENT
INJUNCTION

The United States of America, plaintiff, by its undersigned attorneys, having filed its complaint for injunctive relief against defendants, Bio Health Solutions, LLC (“BHS”), a limited liability company, and Mark Garrison, an individual (collectively, “Defendants”), and Defendants, without admitting or denying the allegations in the Complaint, having appeared and having consented to the entry of this Consent Decree of Permanent Injunction (the “Decree”), without contest and before any testimony has been taken, and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and over all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345 and 21 U.S.C. § 332 and its inherent equitable authority.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399f (the “FDCA”).

3. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined, under the provisions of 21 U.S.C. § 332(a) and the equitable authority of this Court, from directly or indirectly doing or causing to be done any of the following acts: introducing or delivering for introduction into interstate commerce,

1 manufacturing, processing, packaging, labeling, holding, selling, or distributing RenAvast or any
2 other product intended to diagnose, cure, mitigate, treat, or prevent disease, unless and until an
3 approved new animal drug application ("NADA") filed pursuant to 21 U.S.C. § 360b(b) is effective
4 with respect to that product, or that product meets the requirements for the investigational new
5 animal drug exemption pursuant to 21 U.S.C. § 360b(j) and 21 C.F.R. Part 511.

6 4. Upon entry of this Decree, Defendants and each and all of their directors, officers,
7 agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active
8 concert or participation with any of them, who have received actual notice of this Decree by personal
9 service or otherwise, are permanently restrained and enjoined, under the provisions of 21 U.S.C.
10 § 332(a) and the equitable authority of this Court, from directly or indirectly doing or causing to be
11 done any act that violates 21 U.S.C. § 331(a) by introducing and/or causing to be introduced, and/or
12 delivering or causing to be delivered for introduction, into interstate commerce, any new animal drug
13 that is adulterated within the meaning of 21 U.S.C. § 351(a)(5).

14 5. Representatives of FDA shall be permitted, without prior notice and as and when
15 FDA deems necessary, to make inspections of Defendants' places of business, collect samples, and,
16 without prior notice, take any other measures necessary to monitor and ensure continuing
17 compliance with the terms of this Decree. During such inspections, FDA representatives shall be
18 permitted access to Defendants' places of business including, but not limited to, all buildings,
19 equipment, in-process or unfinished and finished materials and products, containers, labeling, and
20 other promotional material therein; to take photographs and make video recordings; to take samples
21 – without charge to FDA – of Defendants' finished and unfinished materials and products,
22 containers and packaging material therein, labeling, and other promotional material; and to examine
23 and copy all records relating to the receipt, manufacturing, holding, and distribution of any and all
24 drugs and their components. The inspections shall be permitted upon presentation of a copy of this
25 Decree and appropriate credentials. The inspection authority granted by this Decree is separate
26 from, and in addition to, the authority to conduct inspections under the FDCA, 21 U.S.C. § 374.

27 6. If, at any time after entry of this Decree, FDA determines, based on the results of an
28 inspection, analyses of samples, a report or data prepared or submitted by Defendants, or any other

1 information, that Defendants have violated the FDCA or its implementing regulations or have failed
2 to comply with the provisions of this Decree, or that additional corrective actions are necessary to
3 achieve compliance with the FDCA, its implementing regulations, and/or this Decree, FDA may, as
4 and when it deems necessary, notify Defendants in writing of the noncompliance and order
5 Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants
6 to immediately take one or more of the following actions:

7 A. Cease all manufacturing, holding, and/or distribution of any and all drug(s);

8 B. Recall specified drugs manufactured, held, and/or distributed by Defendants.

9 Defendants shall, under FDA supervision and pursuant to a plan approved in writing by FDA,
10 destroy all drugs that are in Defendants' possession, custody, or control, for which a recall was
11 initiated. Defendants shall bear the costs of such recall(s), including the costs of destruction and the
12 costs of FDA's supervision at the rates specified in Paragraph 9 of this Decree. Defendants shall be
13 responsible for ensuring that the destruction is carried out in a manner that complies with all
14 applicable federal and state environmental laws; and/or

15 C. Take any other corrective action(s) as FDA, in its discretion, deems necessary
16 to protect the public health or bring Defendants into compliance with the FDCA, its implementing
17 regulations, or this Decree.

18 7. The following process and procedures shall apply when FDA issues an order under
19 Paragraph 6 of this Decree, except as provided in subparagraph (D) below:

20 A. Unless a different time frame is specified by FDA in its order, within ten (10)
21 business days after receiving such order, Defendants shall notify FDA in writing either that:

22 (1) Defendants are undertaking or have undertaken corrective action, in
23 which event Defendants shall also describe the specific action taken or proposed to be taken and the
24 proposed schedule for completing the action; or

25 (2) Defendants do not agree with FDA's order. If Defendants notify FDA
26 that they do not agree with FDA's order, Defendants shall explain in writing the basis for their
27 disagreement. In so doing, Defendants also may propose specific alternative action and specific time
28 frames for achieving FDA's objectives.

1 B. If Defendants notify FDA that they do not agree with FDA's order, FDA will
2 review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as
3 FDA deems appropriate. If FDA affirms or modifies its order, it will explain the basis for its
4 decision in writing. The written notice of affirmation or modification shall constitute final agency
5 action.

6 C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's
7 order, immediately implement the order (as modified, if applicable), and if they so choose, bring the
8 matter before this Court. While seeking Court review, Defendants shall continue to diligently
9 implement FDA's order, unless the Court sets aside, stays, reverses, vacates, or modifies FDA's
10 order. Any review of FDA's decision under this paragraph shall be made in accordance with the
11 terms set forth in Paragraph 14 of this Decree.

12 D. The process and procedures set forth above in subparagraphs A-C above shall
13 not apply to any order issued under Paragraph 6 of this Decree if such order states that, in FDA's
14 judgment, the matter raises significant public health concerns. In such case, Defendants shall
15 immediately and fully comply with the terms of that order. Should Defendants seek to challenge any
16 such order, they may petition this Court for relief while they implement FDA's order. Any review
17 of FDA's decision under this paragraph shall be made in accordance with the terms set forth in
18 Paragraph 14 of this Decree.

19 8. Any cessation of operations or other action described in Paragraph 6 of this Decree
20 shall continue until Defendants receive written notification from FDA that Defendants appear to be
21 in compliance with the FDCA, its implementing regulations, and this Decree, and that Defendants
22 may, therefore, resume operations. Upon Defendants' written request to resume operations, FDA
23 will promptly determine whether it needs to inspect any of Defendants' facilities to determine
24 Defendants' compliance with the law and this Decree. If FDA determines that an inspection is
25 necessary, it will conduct the inspection within sixty (60) calendar days after such determination,
26 and, within thirty (30) calendar days following the close of the inspection, determine whether
27 Defendants appear to be in compliance with the law and this Decree and, if so, FDA will issue to
28 Defendants a written notification permitting resumption of operations. If FDA determines that no

1 inspection is necessary, FDA will decide within forty-five (45) calendar days after receipt of the
2 request whether Defendants appear to be in compliance and, if so, issue to Defendants a written
3 notification permitting resumption of operations. In no circumstances shall FDA's silence be
4 construed as a substitute for written notification. All costs of recall(s) and corrective actions ordered
5 by FDA pursuant to Paragraph 6 of this Decree shall be borne by Defendants. The costs of FDA
6 inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set
7 forth in Paragraph 6 of this Decree shall be borne by Defendants at the rates specified in Paragraph 9
8 of this Decree. This provision shall be separate and apart from, and in addition to, all other remedies
9 available to FDA.

10 9. Defendant BHS shall pay all costs of FDA's supervision, inspections, investigations,
11 analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance
12 with this Decree, at the standard rates prevailing at the time the costs are incurred. As of the date
13 that this Decree is signed by the parties, these rates are: \$89.35 per hour and fraction thereof per
14 representative for inspection work; \$107.90 per hour or fraction thereof per representative for
15 analytical or review work; \$0.575 per mile for travel by automobile; government rate or the
16 equivalent for travel by air or other means; and the published government per diem rate or the
17 equivalent for the areas in which the inspections are performed per representative and per day for
18 subsistence expenses, where necessary. In the event that the standard rates applicable to FDA
19 supervision of court-ordered compliance are modified, these rates shall be increased or decreased
20 without further order of the Court.

21 10. Within ten (10) days after the entry of this Decree, Defendants shall provide a copy of
22 this Decree, by personal service or registered mail, to each and all of their directors, officers, agents,
23 employees, representatives, successors, assigns, attorneys, and any and all persons in active concert
24 or participation with any of them (including "doing business as" entities) (collectively referred to as
25 "Associated Persons"). Within thirty (30) days after entry of this Decree, Defendants shall provide
26 to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating
27 the fact and manner of compliance with the provisions of this Paragraph and identifying the names,
28 addresses, and positions of all persons who have received a copy of this Decree and the manner of

1 notification. In the event that Defendants becomes associated with any additional Associated
2 Person(s) at any time after entry of this Decree, Defendants immediately shall provide a copy of this
3 Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such
4 Associated Person(s). Within thirty (30) days after the commencement of each such association,
5 Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with
6 this Paragraph, identifying the names, addresses, and positions of all Associated Persons who
7 received a copy of this Decree pursuant to this Paragraph, and attaching a copy of the executed
8 certified mail return receipts. Within ten (10) days after receiving a request from FDA for any
9 information or documentation that FDA deems necessary to evaluate Defendants' compliance with
10 this Paragraph, Defendants shall provide such information or documentation to FDA.

11 11. Defendants shall notify FDA in writing at least fifteen (15) days before any change in
12 ownership, character, or name of their businesses, including incorporation, reorganization,
13 bankruptcy, assignment, or sale resulting in the emergence of a successor business or corporation,
14 the creation or dissolution of subsidiaries, or any other change in the corporate structure or identity
15 of the Defendants' business, or in the sale or assignment of any business assets, such as buildings,
16 equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall
17 provide a copy of this Decree to any potential successor or assign at least fifteen (15) days before
18 any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this
19 Paragraph no later than ten (10) days prior to such assignment or change in ownership.

20 12. If Defendants fail to comply with any of the provisions of this Decree, including any
21 time frame imposed by this Decree, then Defendant BHS shall pay to the United States of America:
22 five thousand dollars (\$5,000) in liquidated damages for each violation of the FDCA, its
23 implementing regulations, and/or this Decree, and an additional sum of five thousand dollars
24 (\$5,000) in liquidated damages for each day such violation continues; and further additional sum
25 equal to three times the retail value of any drugs that have been distributed in violation of this
26 Decree. Defendants understand and agree that the liquidated damages specified in this Paragraph are
27 not punitive in nature and their imposition does not in any way limit the ability of the United States
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1 to seek, or the power of the Court to impose, additional criminal or civil penalties or remedies based
2 on conduct that may also be the basis for payment of liquidated damages pursuant to this Paragraph.

3 13. Should the United States of America bring, and prevail in, a contempt action to
4 enforce the terms of this Decree, Defendants shall, in addition to other remedies, pay all attorneys'
5 fees and costs, travel expenses incurred by attorneys and witnesses, expert witness fees,
6 investigational and analytical expenses, and court costs incurred by Plaintiff in bringing such an
7 action.

8 14. Defendants shall abide by FDA's decisions, and FDA's decisions shall be final. All
9 decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested,
10 shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C.
11 § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be
12 based exclusively on the written record before FDA at the time of the decision. No discovery shall
13 be taken by either party.

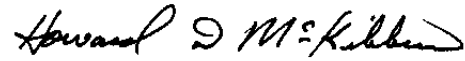
14 15. A party may at any time petition the other party in writing to extend any deadline
15 provided for herein, and such extension may be granted by the other party in its sole discretion
16 without seeking leave of Court.

17 16. All notifications, certifications, reports, correspondence, and other communications to
18 FDA required by the terms of this Decree shall be marked "Consent Decree Correspondence" and
19 shall be addressed to the Director, FDA San Francisco District Office, 1431 Harbor Bay Parkway,
20 Alameda, CA 94502.

21 17. This Court retains jurisdiction of this action and the parties thereto for the purpose of
22 enforcing and modifying this Decree and for the purpose of granting such additional relief as may be
23 necessary or appropriate.

24 18. If Defendants petition the Court for relief from this Decree and, at the time of the
25 petition, in FDA's judgment, Defendants have maintained a state of continuous compliance with this
26 Decree, the Act, and all applicable regulations for the preceding sixty (60) months, Plaintiff will not
27 oppose such petition.
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1 IT IS SO ORDERED, this 10th day of July, 2015.

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5 UNITED STATES DISTRICT JUDGE
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7 Page 8 of Consent Decree of Permanent Injunction
8 USA vs. Bio Health Solutions, LLC and Mark
9 Garrison 3:15-cv-354-HDM-VPC
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1 WE HEREBY AGREE TO THE ENTRY OF THE ABOVE CONSENT DECREE

2 FOR THE DEFENDANTS:

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4 Dated:

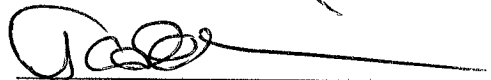
06/19/2015 

5 MARK GARRISON

6 Individually and on behalf of
7 Bio Health Solutions, LLC

8 Dated:

7/1/2015



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6/29/2015



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25 Bio Health Solutions, LLC and

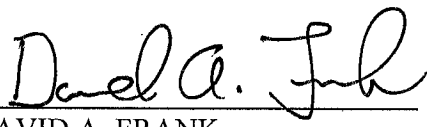
26 Mark Garrison

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